

REMARKS

Claims 9-11, 18-21, 26, 28, and 29 are presently pending. The sole independent claim, claim 9, reads as follows:

Claim 9. A method of treating a skin condition arising from fungal infection, bacterial infection, allergic reaction, or inflammation in a patient in need thereof comprising the step of topically administering an effective amount of a semi-solid composition formulated for topical administration, said composition consisting essentially of a purified polyunsaturated fatty acid fraction extracted from *Nigella sativa* L. seeds and a pharmaceutically acceptable carrier, wherein said polyunsaturated fatty acid fraction consists of polyunsaturated fatty acids and is free of *Nigella sativa* L. saturated fatty acids, sterols, volatile oils, and glyceryl esters.

As discussed in the previous response as well as in the telephone interview of November 10th, none of the prior art references, alone or in combination, disclose or suggest the intentional selection of the polyunsaturated fatty acid component of *Nigella sativa* extract, to the exclusion of other potentially bioactive components such as saturated fatty acids, sterols, volatile oils, and glyceryl esters. Accordingly, Applicant respectfully submits that the pending claims are in condition for allowance and respectfully petitions for an early notification of such. Further to this position, Applicant submits the following remarks:

Rejections under 35 U.S.C. § 103

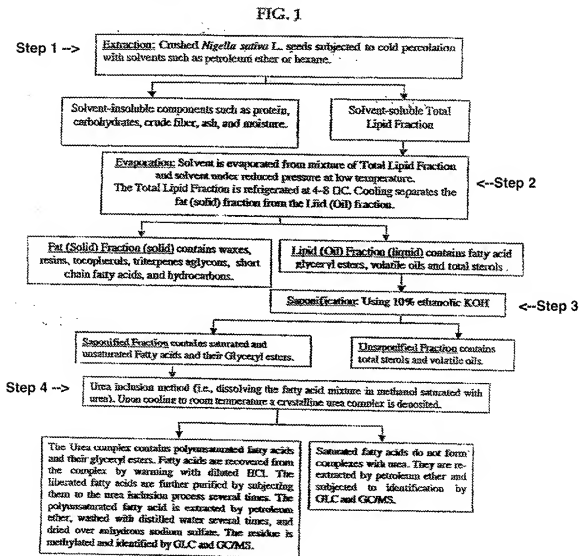
Claims 9-11, 18-21, and 26 stand rejected under 35 U.S.C. § 103(a) as being obvious over Ahmad et al. (US 2005/0058735) in view of Goreja (Black Seed: Nature's Miracle Remedy, 2003), further in view of Berg (Advances in Dermatology, 1988) and Schlenk et al. (JACS, 1950). Dependent claims 28-29 stand rejected under 35 U.S.C. § 103(a) as being obvious over Ahmad, Goreja, Berg and Schlenk as applied to claim 9, further in view of Nickavar (Naturforsch, 2003).

While Applicant continues to dispute the Examiner's interpretation of the Ahmad reference and further submits that the generic teachings of Goreja fail to cure the previously noted deficiencies of Ahmad, for the purposes of this response Applicant wishes to focus on the Schlenk reference and the Examiner's suggestion that it would have been obvious "to utilize the method of Schlenk to isolate the polyunsaturated fraction [from the *Nigella sativa* extract of Ahmad and/or Goreja] with the reasonable expectation of providing a method that is not only effective in treating diaper rash but also a method that is useful in treating intertrigo, dermatitis, bacterial and fungal infections affecting the skin." Non-Final Office action at page 11.

As noted in previous responses, while Applicant does not dispute that the urea inclusion process utilized herein and described by Schlenk et al. was known in the art at the time of invention as a means to enrich an extract in polyunsaturated fatty acids, Applicant respectfully submits that none of the prior art references disclose the desirability of such enrichment.

Rejections based on obviousness cannot be sustained by conclusory statements. *In re Kahn*, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006). The mere fact that references can be combined or modified does not render a resultant combination obvious. *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). Likewise, the fact that a particular group of references demonstrates that each aspect of a claimed invention was individually known in the art is not sufficient to establish a *prima facie* case of obviousness. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). Rather, a legal conclusion of obviousness necessarily requires the provision of some objective reason to combine the reference teachings, some articulated reasoning with some rational underpinning, some teaching, suggestion, or motivation answering the question of why - why one of skill in the art would have so combined the reference teachings. Applicant respectfully submits that the Examiner has failed to answer this question, that the requisite rationale linking Ahmad/Goreja and Schlenk is missing, and thus the conclusion of obviousness is fundamentally flawed. Applicant further submits that the requisite "reasonable expectation of success" is also missing, as combining the teachings as proposed is just as likely to undo the bioactivity of the Ahmad extract as it is to improve it.

As noted previously, Ahmad discloses the use of crude extracts, i.e., ground plant material extracted in a polar solvent and subsequently vacuum concentrated (see Ahmad at paragraphs [0065] and [0129]). In other words, referring to Applicant's process of Figure 1, Ahmad stops after step 2.



As such, Ahmad's botanical extract contains both saturated and unsaturated fatty acids in glyceryl ester form as well as volatile oils and sterols. In contrast, Applicant continues the

purification process to (a) liberate the fatty acids and remove sterols and volatile oils (e.g., via specification - step 3) and (b) remove saturated fatty acids (e.g., via the urea inclusion method), to arrive a purified fatty acid fraction that “consists of polyunsaturated fatty acids and is free of *Nigella sativa* L. saturated fatty acids, sterols, volatile oils, and glyceryl esters”. Nothing in the Ahmad reference, or indeed in any other cited reference, suggests the desirability of performing these additional steps.

The Goreja teaching is similarly restricted, referencing the various uses of whole seeds, aqueous extracts, fixed and essential [i.e., volatile] oils, and essential fatty acids. Neither Goreja nor Ahmad characterize their respective *Nigella sativa* compositions or make any attempt to identify the one or more “medicinal contents” contained therein. In the absence of such characterization data, one cannot reasonably predict whether further processing will enhance or diminish the target activity. In fact, given that the components excluded from Applicant’s formulation (i.e., glyceryl esters, saturated fatty acids, sterols, and/or volatile oils) are known in certain circumstances to possess beneficial biological properties, for example cholesterol lowering activity (See Appendix A), they are just as likely as the purified polyunsaturated fatty acid fraction to be responsible for the desired bioactivity (e.g., immunomodulation). Accordingly, although one of ordinary skill in the art may indeed have been aware of Schlenk’s enrichment process, he would not have been motivated to use it or any other known process to further refine the Ahmad or Goreja extracts, selecting only for the polyunsaturated fatty acid fraction to the exclusion of all others, for fear of accidentally removing the primary bioactive constituent.

Thus, Applicant respectfully submits that the prior art of record fails to disclose or suggest the use of a semi-solid composition formulated for topical administration consisting essentially of a purified *Nigella sativa* polyunsaturated fatty acid fraction that consists only of polyunsaturated fatty acids and expressly excludes other *Nigella* components such as saturated fatty acids, sterols, volatile oils, and glyceryl esters in the treatment of a skin condition arising from fungal infection, bacterial infection, allergic reaction, or inflammation. Accordingly, Applicant respectfully submits that the conclusion of obviousness is in error. Accordingly, Applicant requests reconsideration and withdrawal of the outstanding rejection of claims 9-11, 18-21, 26, 28, and 29 under 35 U.S.C. § 103(a) in view of the remarks herein.

CONCLUSION

The outstanding Office Action set a three-month shortened statutory period for response. Pursuant to the entry of Applicant's petition for a one month extension of time, response is due on or before **December 7, 2009**. Accordingly, Applicant submits that this response is timely and that no additional fee is required. However, in the event that further fees are required to enter the instant response and/or maintain the pendency of this application, the Commissioner is authorized to charge such fees to the undersigned's Deposit Account No. **50-2101**.

If the Examiner has any questions or concerns regarding this communication, she is invited to contact the undersigned.

Respectfully submitted,

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